

FORM PTO-1390 (Modified) U.S. PATENT AND TRADEMARK OFFICE; U.S. DEPARTMENT OF COMMERCE (REV. 7-2005)		ATTORNEY'S DOCKET NUMBER 282276US0PCT
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 807584096
INTERNATIONAL APPLICATION NO. PCT/EP04/07882	INTERNATIONAL FILING DATE 15 July 2004	PRIORITY DATE CLAIMED 15 July 2003
TITLE OF INVENTION MULTIPARTICLE PHARMACEUTICAL DOSAGE FORM CONTAINING A MUCCOADHESIVELY FORMULATED PEPTIDE OR PROTEIN ACTIVE SUBSTANCES METHOD FOR PRODUCING SAID PHARMACEUTICAL DOSAGE FORM		
APPLICANT(S) FOR DO/EO/US Rosario LIZIO, et al.		MAIL STOP PCT
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<ol style="list-style-type: none"> 1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a submission under 35 U.S.C. 371. 2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371. 3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (24) indicated below. 4. <input type="checkbox"/> The US has been elected (Article 31). 5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371 (c)(2)) <ol style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input checked="" type="checkbox"/> has been communicated by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). 6. <input checked="" type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). <ol style="list-style-type: none"> a. <input checked="" type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). 7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3)) <ol style="list-style-type: none"> a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input checked="" type="checkbox"/> have not been made and will not be made. 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). 9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)). 10. <input type="checkbox"/> An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)). 11. <input type="checkbox"/> A copy of the International Preliminary Examination Report (PCT/IPEA/409). 12. <input checked="" type="checkbox"/> A copy of the International Search Report (PCT/ISA/210). 		
Items 13 to 23 below concern document(s) or information included:		
<ol style="list-style-type: none"> 13. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 14. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 15. <input checked="" type="checkbox"/> A FIRST preliminary amendment. 16. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment. 17. <input type="checkbox"/> A substitute specification. 18. <input type="checkbox"/> A power of attorney and/or change of address letter. 19. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825. 20. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4). 21. <input type="checkbox"/> A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4). 22. <input type="checkbox"/> Express Mail Label No. 		

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO (if known, see 37 CFR 1.5) 107504096	INTERNATIONAL APPLICATION NO. PCT/EP04/07882	ATTORNEY'S DOCKET NUMBER 282276US0PCT																																																																																																								
23. Other items or information: Application Data Sheet/Notice of Priority/PCT/IB/304/PCT/IB/308/ PTO-1449/Cited References (13)/Statement of Relevancy																																																																																																										
<table border="1"> <thead> <tr> <th colspan="2">The following fees have been submitted:</th> <th>CALCULATIONS</th> <th>PTO USE</th> </tr> </thead> <tbody> <tr> <td colspan="2">24. <input checked="" type="checkbox"/> Basic national fee</td> <td>\$300</td> <td>\$300.00</td> </tr> <tr> <td colspan="2">25. <input checked="" type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article</td> <td>\$0</td> <td>\$200.00</td> </tr> <tr> <td colspan="2">All other situations.....</td> <td>\$200</td> <td></td> </tr> <tr> <td colspan="2">26. <input checked="" type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the International preliminary examination report by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)...</td> <td>\$0</td> <td></td> </tr> <tr> <td colspan="2">Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the as an International Searching Authority.....</td> <td>\$100</td> <td>\$400.00</td> </tr> <tr> <td colspan="2">International Search Report prepared by an ISA other than the US and provided to the previously communicated to the US by the IB.....</td> <td>\$400</td> <td></td> </tr> <tr> <td colspan="2">All other situations.....</td> <td>\$500</td> <td></td> </tr> <tr> <td colspan="2">TOTAL OF 24, 25 and 26 =</td> <td>\$</td> <td>\$900.00</td> </tr> <tr> <td colspan="2"><input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(i)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.</td> <td></td> <td></td> </tr> <tr> <td>Total Sheets</td> <td>Extra Sheets</td> <td>Number of each additional 50 or fraction thereof (round up to a whole)</td> <td>RATE</td> </tr> <tr> <td>- 100 =</td> <td>0 /50 =</td> <td>0</td> <td>x \$250.00</td> </tr> <tr> <td colspan="4">Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).</td> </tr> <tr> <td>CLAIMS</td> <td>NUMBER FILED</td> <td>NUMBER EXTRA</td> <td>RATE</td> </tr> <tr> <td>Total claims</td> <td>32 - 20 =</td> <td>12</td> <td>x \$50.00</td> </tr> <tr> <td>Independent claims</td> <td>1 - 3 =</td> <td>0</td> <td>x \$200.00</td> </tr> <tr> <td colspan="2">MULTIPLE DEPENDENT CLAIMS (if applicable)</td> <td><input type="checkbox"/> +</td> <td>\$360.00</td> </tr> <tr> <td colspan="4">TOTAL OF ABOVE CALCULATIONS =</td> </tr> <tr> <td colspan="2"><input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.</td> <td>\$</td> <td>\$0.00</td> </tr> <tr> <td colspan="4">SUBTOTAL =</td> </tr> <tr> <td colspan="2">Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).</td> <td>\$</td> <td>\$0.00</td> </tr> <tr> <td colspan="4">TOTAL NATIONAL FEE =</td> </tr> <tr> <td colspan="2">Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property +</td> <td>\$</td> <td>\$0.00</td> </tr> <tr> <td colspan="4">TOTAL FEES ENCLOSED =</td> </tr> <tr> <td colspan="2"></td> <td>Amount to be</td> <td>\$</td> </tr> <tr> <td colspan="2"></td> <td>Amount to be</td> <td>\$</td> </tr> </tbody> </table>			The following fees have been submitted:		CALCULATIONS	PTO USE	24. <input checked="" type="checkbox"/> Basic national fee		\$300	\$300.00	25. <input checked="" type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article		\$0	\$200.00	All other situations.....		\$200		26. <input checked="" type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the International preliminary examination report by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)...		\$0		Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the as an International Searching Authority.....		\$100	\$400.00	International Search Report prepared by an ISA other than the US and provided to the previously communicated to the US by the IB.....		\$400		All other situations.....		\$500		TOTAL OF 24, 25 and 26 =		\$	\$900.00	<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(i)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.				Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole)	RATE	- 100 =	0 /50 =	0	x \$250.00	Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).				CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	Total claims	32 - 20 =	12	x \$50.00	Independent claims	1 - 3 =	0	x \$200.00	MULTIPLE DEPENDENT CLAIMS (if applicable)		<input type="checkbox"/> +	\$360.00	TOTAL OF ABOVE CALCULATIONS =				<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.		\$	\$0.00	SUBTOTAL =				Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).		\$	\$0.00	TOTAL NATIONAL FEE =				Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property +		\$	\$0.00	TOTAL FEES ENCLOSED =						Amount to be	\$			Amount to be	\$
The following fees have been submitted:		CALCULATIONS	PTO USE																																																																																																							
24. <input checked="" type="checkbox"/> Basic national fee		\$300	\$300.00																																																																																																							
25. <input checked="" type="checkbox"/> Examination fee (37 CFR 1.492(c)) If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article		\$0	\$200.00																																																																																																							
All other situations.....		\$200																																																																																																								
26. <input checked="" type="checkbox"/> Search fee (37 CFR 1.492(b)) If the written opinion of the ISA/US or the International preliminary examination report by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4)...		\$0																																																																																																								
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the as an International Searching Authority.....		\$100	\$400.00																																																																																																							
International Search Report prepared by an ISA other than the US and provided to the previously communicated to the US by the IB.....		\$400																																																																																																								
All other situations.....		\$500																																																																																																								
TOTAL OF 24, 25 and 26 =		\$	\$900.00																																																																																																							
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(i)). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.																																																																																																										
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole)	RATE																																																																																																							
- 100 =	0 /50 =	0	x \$250.00																																																																																																							
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).																																																																																																										
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE																																																																																																							
Total claims	32 - 20 =	12	x \$50.00																																																																																																							
Independent claims	1 - 3 =	0	x \$200.00																																																																																																							
MULTIPLE DEPENDENT CLAIMS (if applicable)		<input type="checkbox"/> +	\$360.00																																																																																																							
TOTAL OF ABOVE CALCULATIONS =																																																																																																										
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.		\$	\$0.00																																																																																																							
SUBTOTAL =																																																																																																										
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).		\$	\$0.00																																																																																																							
TOTAL NATIONAL FEE =																																																																																																										
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40 per property +		\$	\$0.00																																																																																																							
TOTAL FEES ENCLOSED =																																																																																																										
		Amount to be	\$																																																																																																							
		Amount to be	\$																																																																																																							

10/1564096

PTO-1390 (Rev. 07-2005)
Approved for use through 3/31/2007. OMB 0651-0021

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

JAP20 Rev 11/07/2006 11 JAN 2006

- a. A check in the amount of \$ _____ to cover the above fees is enclosed.
- b. Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.
- c. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 15-0030. A duplicate copy of this sheet is enclosed.
- d. Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

Customer Number
22850

SIGNATURE

Surinder Sachar

NAME

24,618

REGISTRATION NUMBER

Jan 11 2006

DATE

Surinder Sachar
Registration No. 34,423